IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

SUSAN SWICEGOOD, Plaintiff, v. PLIVA, INC., et al., Defendants.	CIVIL ACTION FILE NO. 1:07-CV-1671-TWT

ORDER

This is a products liability action. It is before the Court on the Motion to Dismiss of the Defendants Wyeth and Schwarz [Doc. 14]. For the reasons set forth below, the motion is GRANTED.

I. Background

The Plaintiff, Susan Swicegood, alleges that she was seriously injured as a result of an adverse reaction to the generic equivalent of the prescription drug Reglan. The Plaintiff alleges that Defendant Pliva manufactured the generic Reglan - or metoclopramide - that she ingested. The Plaintiff alleges that, as a result of taking the generic Reglan to treat nausea, she developed neurological injuries, including the condition tardive dystonia. The Defendant Barr Pharmaceuticals ("Barr") is the successor in interest to Defendant Pliva. Defendant Wyeth is the successor in interest

to A.H. Robins Company, who first obtained FDA approval for Reglan. The Defendant Wyeth manufactured Reglan until December 2001. Defendant Schwarz Pharma, Inc. ("Schwarz") purchased the rights to distribute Reglan tablets in December 2001 from Wyeth.

The Plaintiff alleges that she was prescribed Reglan in April 2005, and that her pharmacist dispensed to her generic Reglan manufactured by Defendant Pliva. The Plaintiff took the generic Reglan until July 2005. The Plaintiff claims that the Defendants, collectively, knew that long-term use of Reglan posed a greater risk of causing tardive dystonia than they disclosed to the FDA or the public. Although the Plaintiff alleges she ingested generic Reglan, she claims that Defendants Wyeth and Schwarz should be held liable because their alleged improper labeling of Reglan ensured that generic Reglan would likewise be improperly labeled. Defendants Wyeth and Schwarz now move to dismiss all claims against them. The facts relevant to the motion are undisputed.

II. Motion to Dismiss Standard

A complaint should be dismissed under Rule 12(b)(6) only where it appears that the facts alleged fail to state a plausible claim for relief. Bell Atlantic v. Twombly, 127 S. Ct. 1955, 1965-66 (2007); Fed. R. Civ. P. 12(b)(6). A complaint may survive a motion to dismiss for failure to state a claim, however, even if it is improbable that

a plaintiff would be able to prove those facts, and even if the possibility of recovery is extremely remote and unlikely. Twombly, 127 S. Ct. at 1965 (citations and quotations omitted). In ruling on a motion to dismiss, the court must accept the facts pleaded in the complaint as true and construe them in the light most favorable to the plaintiff. See Quality Foods de Centro America, S.A. v. Latin American Agribusiness Dev. Corp., S.A., 711 F.2d 989, 994-95 (11th Cir. 1983); see also Sanjuan v. American Bd. of Psychiatry and Neurology, Inc., 40 F.3d 247, 251 (7th Cir. 1994) (noting that at the pleading stage, the plaintiff "receives the benefit of imagination"). Generally, notice pleading is all that is required for a valid complaint. See Lombard's, Inc. v. Prince Mfg., Inc., 753 F.2d 974, 975 (11th Cir. 1985), cert. denied, 474 U.S. 1082 (1986). Under notice pleading, the plaintiff need only give the defendant fair notice of the plaintiff's claim and the grounds upon which it rests. See Erickson v. Pardus, 127 S. Ct. 2197, 2200 (2007) (citing Twombly, 127 S. Ct. at 1964).

III. Discussion

A. Strict Liability

As to all Defendants, the Plaintiff's first theory of liability is strict liability. Georgia's products liability statute, O.C.G.A. § 51-1-11(b)(1), provides that:

> The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any natural person who may use, consume, or reasonably be affected by the property and who suffers injury to his person or

> property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

Id. Defendants Wyeth and Schwarz argue that, under Georgia law, they can only be liable if the Plaintiff was exposed to their products. Georgia courts "have held that unless the manufacturer's defective product can be shown to be the proximate cause of the injuries there can be no recovery. . . . Thus, [the Plaintiff] needed to establish that the product or products that allegedly caused [the injury] were, in fact, manufactured or supplied by the defendants in this case." Hoffman v. AC&S, Inc., 248 Ga. App. 608, 610-11 (2001). To be sure, the proximate cause issue in Hoffman - ascertaining the identity of an asbestos manufacturer - differs slightly from the one in this case. Nonetheless, the language in Hoffman is sufficiently clear to say with confidence that a manufacturer in Georgia can only be liable for strict products liability if it manufactured the allegedly harmful goods. The Plaintiff does not specifically rebut this assertion - or generally defend her strict products liability claim at all - in her Response Brief. Consequently, it is appropriate to dismiss the Plaintiff's strict products liability claim.

B. Negligence

The Plaintiff alleges that Wyeth and Schwarz were negligent in their labeling of Reglan, and the testing and post-marketing surveillance of the drug. Claims for

negligence against a manufacturer may be pled independent of strict liability claims. See Battersby v. Boyer, 241 Ga. App. 115, 116-17 (1999) (recognizing failure to warn claim based on negligence is distinct from strict products liability claims). Under Georgia law, a manufacturer may be liable for failure to warn "if it fails to (1) adequately communicate the warning to the ultimate user or (2) fail[s] to provide an adequate warning of the product's potential risks." Watkins v. Ford, 190 F.3d 1213, 1219 (11th Cir. 1999). Even assuming that the Plaintiff could show that the Defendants failed to adequately warn her of a dangerous condition, the claim should be dismissed.

The Defendants argue that the Plaintiff's negligence claim should be dismissed because she failed to allege that Wyeth and Schwarz manufactured or distributed the generic Reglan tablets. Under Georgia law, a manufacturer may be liable under products liability when its product causes injury and was "sold by the manufacturer." O.C.G.A. § 51-1-11; see also Hoffman, supra. For example, to be liable for failure to warn, the defendant must be a supplier of the product, which includes manufacturers, retailers, sellers, and distributors of the chattel. Potts v. UAP-GA AG CHEM, Inc., 256 Ga. App. 153, 158 (2002). Again, the Plaintiff does not allege that Wyeth and Schwarz manufactured the Reglan that caused her alleged injuries. The Plaintiff's products liability claims based in negligence must likewise fail.

C. Fraudulent and Negligent Misrepresentation

The Plaintiff also argues that Wyeth and Schwarz should be liable for negligently or fraudulently misrepresenting the true nature of the risk of Reglan products. In order to state a claim for fraudulent misrepresentation, there must be (1) false representation by a defendant; (2) scienter; (3) intent to induce the plaintiff to act or refrain from acting; (4) justifiable reliance by the plaintiff; and (5) resulting damage to the plaintiff. Potts, 256 Ga. App. at 153, 156. "The same principles apply to both fraud and negligent misrepresentation." Anderson v. Atlanta Committee for Olympic Games, Inc., 261 Ga. App. 895, 900 (2003). The claim for negligent misrepresentation stems from the policy that "[o]ne who supplies information during the course of his business, profession, employment, or in any transaction in which he has a pecuniary interest has a duty of reasonable care and competence to parties who rely upon the information in circumstances in which the maker was manifestly aware of the use to which the information was to be put and intended that it be so used. This liability is limited to a foreseeable person or limited class of persons for whom the information was intended, either directly or indirectly." Benefit Support, Inc. v. Hall County, 281 Ga. App. 825, 835 (2006).

The Plaintiff contends that Reglan's safety information was "in the exclusive control of Wyeth and Schwarz and was exclusively known by them" and the public

"depended on the accuracy" of safety information provided by Wyeth and Schwarz. (Compl. ¶ 112). The Defendants first argue for dismissal because the name brand manufacturers owe no duty to consumers of the generic manufacturers. The Plaintiff attempts to show that a duty was created under both state and federal law. First, the Plaintiff argues that Wyeth and Schwarz should be liable because, under Georgia law, "a person may be held liable for the negligent performance of a voluntary undertaking." Osowski v. Smith, 262 Ga. App. 538, 540 (2003). Georgia has adopted the "Good Samaritan" doctrine set forth in the Restatement (Second) of Torts, § 324A. Davenport v. Cummins Alabama, Inc., 284 Ga. App. 666, 672-73 (2007). Section 324A provides:

> One who undertakes, gratuitously or for consideration, to render services to another which he should recognize as necessary for the protection of a third person or his things, is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care if to protect his undertaking, if (a) his failure to exercise reasonable care increases the risk of such harm, or (b) he has undertaken to perform a duty owed by the other to the third person, or (c) the harm is suffered because of reliance of the other or the third person upon the undertaking.

Id. According to the Plaintiff, Wyeth and Schwarz voluntarily became the "Referenced Listed Drug Holder" for metoclopramide products, which obliged them to update the safety information for the drug to the public as necessary. For this proposition, the Plaintiff cites 21 C.F.R. § 314.50(d)(5)(vi)(b), which is part of the regulatory scheme of the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21

U.S.C. § 301, *et seq*. This regulation obligates a new drug applicant to keep the drug's safety information up-to-date. Id.

The Court agrees with the Defendants that the obligation is only voluntary in the sense that Wyeth and Schwarz chose to market their drug; once a manufacturer makes that decision, they are obligated to submit an application for approval to market the drug. The regulation does not require a name brand manufacturer to ensure that the generic brand's label is accurate. Further, solely by providing the initial safety labeling, Wyeth and Schwarz did not assume the duty of labeling generic Reglan. Smallwood v. U.S., 988 F. Supp. 1479, 1482 (S.D. Ga. 1997) ("The Eleventh Circuit has stated that for liability to exist under [§ 324A] the duty in question must be completely assumed by the gratuitous party."). After all, the generic manufacturer Pliva used its own label on its products, which it was free to alter with FDA approval. As a result, the dearth of authority holding one manufacturer liable for another's product outweighs any considerations of degrees of voluntariness to become the referenced licensed drug holder.

The Defendants argue that the misrepresentation claims are merely masquerading as products liability claims. Any theory of recovery, they argue, necessarily relies upon "the fact that Plaintiff's claims are all grounded on an alleged injury from a product." (Defs.' Mot. to Dismiss, at 11). The Plaintiff counters by

highlighting that Georgia courts have held that claims for negligence are viable independent of strict products liability. Battersby, 241 Ga. App. at 116-17. The cases the Plaintiff relies on, however, only allow negligence claims in the context of failure to warn or negligent design claims. See Banks v. ICI Americas, 266 Ga. 607 (1996) (allowing claim for negligent design in products liability case); Moore v. ECI Management, 246 Ga. App. 601 (2000) (recognizing distinct claim in negligence for failure to warn). In the absence of clear precedent, I am not prepared to recognize the viability of misrepresentation claims distinct from products liability or failure to warn claims. In my view, misrepresentation claims against a manufacturer properly collapse into the failure to warn claims. The Plaintiff cannot recover against Wyeth and Schwarz under a failure to warn theory. See Potts v. UAP-GA AG CHEM, Inc., 256 Ga. App. 153, 158 (2002) (holding that for defendant to be liable for failure to warn, the defendant must be a supplier of the product, which includes manufacturers, retailers, sellers, and distributors of the chattel). Although Potts itself contemplated that a misrepresentation claim could be distinct from a failure to warn claim, only the failure to warn claim dealt with a products liability claim. In Potts, the court allowed the decedent's estate sued to recover from the decedent's former employer for alleged misrepresentations made to the decedent's physician about the decedent's *exposure* to chemicals. Id. at 153-55. The physician relied on the misrepresentations and,

consequently, tailored an ineffective treatment to the victim that led to his death. Id. On the other hand, the summarily adjudicated failure to warn claim was against a hands-off financier defendant of the product. Id.

There is some Georgia authority for subjecting multiple manufacturing defendants to liability for industry-wide misrepresentations. In Holland v. Sanfax Corp., 106 Ga. App. 1, 7-8 (1962), the plaintiff sued multiple manufacturers of a product for misrepresentations about a product's safety. The plaintiff was seeking recovery from "the use of *one of defendants'* products." Id. at 2 (emphasis supplied). The court found that the chemical defendants, "in selling and recommending their product, for use for cleaning drains, with actual knowledge that it was dangerous for this purpose, knowingly made a false representation as to the quality of the product." Id. However, I am not convinced that this decades-old Court of Appeals opinion would mandate the decision in this case. In the instant case, there is no dispute about who manufactured the harmful product and the state law claims must be viewed in the context of the complex regulatory and statutory scheme of the FDCA. In short, I believe that permitting claims in negligence against a manufacturer for one of its competitor's products would "result in an unprecedented departure from traditional Georgia tort law." Starling v. Seaboard Coast Line R. Co., 533 F. Supp. 183, 193 (S.D. Ga. 1982).

The Plaintiff contends that federal law, not just state law, creates a duty towards consumers of even generic prescription drugs. It is true that under the FDCA, all manufacturers have an affirmative duty to update the safety information as needed. For example, 21 C.F.R. § 314.80 outlines the general requirements for a manufacturer's affirmative, postmarket reporting of any adverse drug experiences. It requires, among other things, the reporting of adverse drug experiences that are both serious and unexpected within 15 days. 21 C.F.R. § 314.80 (c)(1)(i). Notably, the Plaintiff has failed to point to any specific tort liability created by the statutory scheme. At best, the Plaintiff has steered the Court to legislative history of the most recent amendments to the FDCA. (Pl.'s Br. in Opp'n to Defs.' Mot. for Summ. J., at 4, n.5) (citing 153 Cong. Rec. S11831) (daily ed. Sept. 20, 2007) (statement of Sen. Kennedy that "[r]egulation by the Food and Drug Administration and product liability lawsuits against the manufacturers of harmful drugs work together to protect consumers."). General citations of the value of tort liability in the legislative history fall short of the authority needed to hold a manufacturer liable for a product it did not make.

The Plaintiff argues further that liability for brand name manufacturers is appropriate under the FDCA because generic manufacturers are required to use the safety information provided by the name brand manufacturer until the abbreviated

new drug application is approved by the FDA. It is true that Congress enacted the Hatch-Waxman Amendments of the FDCA with the goal of allowing generic manufacturers to rely on the safety information of the name brand manufacturer. See Andrx Pharmaceuticals, Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002). In this case, however, the Plaintiff concedes that the FDA long ago gave approval of the abbreviated applications for generic Reglan. As such, the generic manufacturer was not bound by Wyeth or Schwarz's label. (See Pl.'s Br. in Opp'n to Defs.' Mot. to Dismiss, at 9, n.14; id. at 19, n.23). Defendant Pliva had the ability - albeit with approval from the FDA - to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or "delete false misleading, or unsupported indications for use." Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514, 523 (E.D. Pa. 2006) (explaining the FDA's interpretation of 21 C.F.R. § 314.70(c)(6)(iii)(A)).

This Court joins with other courts nationwide in rejecting the claim that the manufacturer of the branded product is liable for misrepresentation in the labeling of the generic product. I am persuaded by the leading authority for this line of cases, the Fourth Circuit's decision in Foster v. American Home Products Corp., 29 F.3d 165 (4th Cir. 1994). In Foster, the court held, among other things, that it is imprudent to hold a party liable for any manufacturing mistakes by another company. "Name brand manufacturers undertake the expense of developing pioneer drugs . . . Generic

manufacturers avoid these expenses by duplicating successful pioneer drugs and their labels." Id. at 170. Further, the generic manufacturer benefits from exposure of the name brand drug, and consequently the generic manufacturer can ride "on the coattails of its advertising." Id. Additionally, perhaps most importantly, the name manufacturer has no control over the manufacturing process of its generic competitor. Id. Taken together, these factors seem especially unfair to hold a name manufacturer liable for its generic competitors' mistakes. As such, I find that the misrepresentation claims must fail under both federal and state law.[1]

D. Concealment

The Plaintiff's claim for concealment should be dismissed. In Georgia, a claim for concealment is recognized when one makes a direct inquiry to a defendant and the defendant evades the truth. American Petroleum Products, Inc. v. Mom & Pop Stores, Inc., 231 Ga. App. 1 (1998). The Plaintiff has not alleged that she specifically asked anyone about the risk of tardive dystonia of Reglan (generic or otherwise).

E. Breach of Implied Warranties

[1]Although it does not impact the outcome of this case, I note that Wyeth and Schwarz have not argued for dismissal based upon federal statutory preemption. Georgia courts have held that state common law claims are not preempted by the FDCA. Bryant v. Hoffmann-La Roche, Inc., 262 Ga. App. 401, 402 (2003). The United States Supreme Court will address whether the FDCA preempts such state law claims in its upcoming term.

Wyeth and Schwarz move to dismiss the Plaintiff's claims for breach of implied warranties. Wyeth and Schwarz argue that liability for breach of implied warranties may only attach if a defendant is the seller of the goods at issue. Georgia's statutory scheme for implied warranties does not contemplate holding one liable for another manufacturer's product. See O.C.G.A. § 11-2-314 ("warranty that the goods shall be merchantable is implied in a contract for sale if the *seller* is a merchant with respect to goods of that kind.") (emphasis supplied); O.C.G.A. § 11-2-315. The Plaintiff does not specifically address how her theory fits within the statutory scheme in her Response Brief. The implied warranty claims against Wyeth and Schwarz should be dismissed.

IV. Conclusion

For the reasons set forth above, the Defendants Wyeth and Schwarz's Motion to Dismiss [Doc. 14] is GRANTED.

SO ORDERED, this 2 day of April, 2008.

/s/Thomas W. Thrash
THOMAS W. THRASH, JR.
United States District Judge